NEWTON LABORATORIES, INC.
HOMEOPATHIC MEDICINE

Over The Counter Remedies • **SIMILIA** *for Health Practitioners* • *Newton Homeopathy For People & Pets*

Dockets Management Branch
HFA-305
Food and Drug Administration, Room 1-23
12420 Park Lawn Drive
Rockville MD 20857

From: Sandra K. Donarski

4 May, 1999

Dear Sirs,

This is in regards to a letter I was Faxed on 3.22.99, about a formal "call for data" on mercury in drugs. I have been on an extended leave of absence due to health problems and have only started work again this past week. On my desk was this Fax that came while I was out. The letter stated that we were to respond by 20 April 1999. That deadline has past but I am attending to the matter. I am in process of completing the information requested and I should have it ready in 2-3 weeks to send to you.

This letter is to let you know that we are complying with your request and will have the information as soon as possible. If you need to contact me about this matter please feel free to call , write or Fax me. I am still not working full time bur do get into the office a couple times a week.

Sincerely,

Sandra K Donarski

Sandra K. Donarski
Director of Operations

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98N-1109

Office: (770) **922-2644** • Toll-Free (800) **448-7256** • Toll-Free Fax: (800) **760-5550**
2360 Rockaway Industrial Boulevard, Conyers, Georgia 30012
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AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

TELEFAX TELEFAX

To: **A.A.H.P. MEMBERS** **U R G E N T**

From: **Eric L. Foxman, Sec.**

Date: 22 March 1999 Subject: Formal Submission of Mercury Data

Dear Friends,

We thank the companies who submitted information for the A.A.H.P. survey on mercury in homeopathic products. This survey was in response to an informal request from FDA.

HOWEVER ... ...

It has come to our attention that FDA has made a **formal** "call for data" on mercury in drugs. This appeared in a Federal Register Notice (12/14/99). This is a task required of FDA by the FDA Modernization Act. The agency has specificially included homeopathic drug products in the "call for data."

FDA must compile this information whether or not companies assist them. [This means that FDA may sned out field inspectors to those homeopathic manufacturers that have not submitted information; such an inspection may blossom to cover much more than just the requested information. Your action now could prevent such an inspection.]

FDA requests the submission of data for each product that contains "intentionally added" mercury compounds – whether as active or inactive components:

1. The name of the commercial product
2. The chemical name (USAN or established name if none exists) of the mercury compound(s) in the drug product; the HPUS name will suffice for active ingredients
3. The quantitative amount of the mercury compound in the drug product. (Include if quantity per dose or quantity per product [ounce or gram] and whether calculated on weight to weight or weight to volume basis, if applicable.)
4. The purpose of the mercury compound in the product. If active, the pharmacologic use must be stated ["Homeopathic" should be sufficient]; if inactive, the function (e.g. preservative, etc.)
5. Estimate of the amount of mercury compound used annually in producing the product
6. A copy of the product's labeling must be included.

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The requested data must be submitted in duplicate, and all submitted information (unless stated on the labeling) will be treated as confidential. The formal date for submission was 15 March, however, I have spoken with Mr. Benson of FDA's OTC Drug Branch and he indicated that submission of date up to 20 April 1999 will be fine.

Information should be identified as *"Submission of Data as requested by 63 Reg. 68775 12/14/99"*, and must be submitted to:

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All members of A.A.H.P. are encouraged to respond as soon as possible and submit the requested information prior to 20 April 1999. A possible format for the submission is attached.

With Warm Greetings,

Eric L. Foxman, R.Ph.
Secretary, A.A.H.P.

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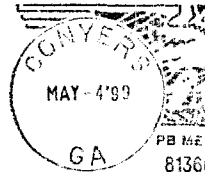
HOMEOPATHY
The Natural Medicine



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